DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 19, 2014

Emmy Medical
% Christine Santagate
Consultant
R & Q Solutions
15 Standish Rd
Norfolk, MA 02056

Re: K142194
Trade/Device Name: CystoSure™ Urinary Access System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ, EZL
Dated: November 13, 2014
Received: November 20, 2014

Dear Christine Santagate,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K142194

Device Name: CystoSure Urinary Access System

Indications for Use:

The CystoSure™ Urinary Access System provides catheterization and visualization for the female urinary bladder.
The CystoSure™ rigid metal scope is used to visualize the urinary bladder for diagnostic procedures.
The CystoSure™ access catheter accessory provides urethral urinary catheterization and postoperative bladder irrigation/lavage with the addition of a sealed port for passage of the CystoSure™ scope.

Prescription Use ___X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Emmy Medical, LLC
Premarket Notification 510(k) K142194
CystoSure Urinary Access System
December 18, 2014

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
K142194

Submitter Information

Submitter's Name: Ron Adams
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Contact Person: Ron Adams
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Date Prepared: April 30, 2014

Device Trade Name: **CystoSure Urinary Access System**

Common/Usual Name: Cystoscope and Accessories, Flexible/Rigid

Class: II

Product Code(s):
Predicate: FAJ
Accessory: EZL

Regulation Number(s):
Predicate: 21 CFR 876.1500
Accessory: 21 CFR 876.5130

Predicate Device (s):
Cystoscope: K040390 Stryker Urology and Gynecology Hardware System
Reference: K080560 Henke Sass Wolf of America Arthroscope

Access Catheter References:
K910486 CR Bard, Bardex® Lubricath™ Foley Catheter
K063442 Degania Silicone All Silicone Foley Catheter, 2-Way, 3-Way and with Temperature Sensor
K132686 Degania Silicone, Ltd. Aquarius Enteral Extension Set

PREMARKET NOTIFICATION FOR THE
CystoSure Urinary Access System

Emmy Medical, LLC
Premarket Notification 510(k) K142194
CystoSure Urinary Access System
December 18, 2014

Device Description:

The Emmy Medical CystoSure Urinary Access System is intended for use in the diagnostic visualization of the female bladder. The CystoSure cystoscope is a reusable, rod lens optic that can be used with standard O.R. camera couplers and light guides. The length and field of view of the Emmy Medical cystoscope are optimized for inspection of the female bladder. The Emmy Medical cystoscope does not include the traditional outer sheath as those functions are provided by the access catheter accessory.

The CystoSure Access Catheter accessory provides a single use access catheter with four ports: One for bladder drainage, one for bladder irrigation, one for balloon inflation and one for the CystoSure cystoscope. The access catheter encompasses only one balloon size (5 cc) and length (female only) and it does not include any hydrophilic or antimicrobial coatings or features to make it radiopaque.

Indications for Use:

The CystoSure™ Urinary Access System provides catheterization and visualization for the female urinary bladder.
The CystoSure™ rigid metal scope is used to visualize the urinary bladder for diagnostic procedures.
The CystoSure™ access catheter accessory provides urethral urinary catheterization and postoperative bladder irrigation/lavage with the addition of a sealed port for passage of the CystoSure™ scope.

Substantial Equivalence:

The Emmy Medical CystoSure Urinary Access System is substantially equivalent in design, materials, construction and intended use as that of the predicate devices. The principal of operation of both devices are identical. Since the Emmy Medical CystoSure Urinary Access System has the same intended use and technological characteristics as the predicate devices, it does not raise any new safety or efficacy concerns when compared to the similar legally marketed devices.

The descriptive characteristics demonstrate that the Emmy Medical CystoSure Urinary Access System is substantially equivalent to the predicate devices and is capable of safely and accurately performing the stated intended use.

Summary of Technological Characteristics:

The technological characteristics of the proposed devices and predicate devices have the same configurations and intended use, are made from the same materials and manufacturing processes, and utilize the same sterilization methods and packaging configurations. The CystoSure catheter adds a fourth port that enables the CystoSure scope to be passed through the central lumen of the catheter.

Support of Substantial Equivalence:

Nonclinical testing of critical performance aspects plus biocompatibility and sterilization validation test reports demonstrate that the proposed devices are substantially equivalent to the predicate devices and they are capable of safely and accurately performing the stated intended use.

Conclusion:

The Emmy Medical CystoSure Urinary Access System is substantially equivalent to the predicate devices in materials, manufacturing processes plus performance and safety characteristics.